

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of
the United Nations



World Health
Organization

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - Fax: (+39) 06 5705 4593 - E-mail: codex@fao.org - www.codexalimentarius.org

Agenda Item 11a

CRD 10
Original language only

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

Thirty-seventh Session
Bad Soden a.T. – Germany
23 – 27 November 2015

OTHER BUSINESS AND FUTURE WORK

A) METHODS OF ANALYSIS IN THE STANDARD FOR INFANT FORMULA AND FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS (CODEX STAN 72-1981)

Comments of Brazil, Colombia, Ecuador, European Union, Indonesia, Mali, Mexico, Morocco and African Union

BRAZIL

General Comments

Brazil appreciates the work done by the United States of America and presents the following comments on the proposals for technical review, typing, endorsement, and inclusion in the Recommended Methods of Analysis and Sampling (CODEX STAN 234-1999) in Part A, section “Foods for Special Dietary Uses”, of the eight methods of analysis for nutrients in infant formula (vitamin B12, myo-Inositol, chromium, selenium, molybdenum, nucleotides, vitamins A and E, fatty acid profile, iodine, and pantothenic acid).

Specific Comments

- In consistency with the Procedural Manual, 23rd, page 68, we consider that, preferably, it should be presented the performance criteria for the methods of analysis for the proposed nutrients in infant formula:

“General Criteria for the Selection of Methods of Analysis using the Criteria Approach”

In the case of Codex Type II and Type III methods, method criteria may be identified and values quantified for incorporation into the appropriate Codex commodity standard” (Procedural Manual, 23rd, page 68).

The instructions for the development of specific criteria are outlined in Table 1 of the Procedural Manual, 23rd, page 70: Guidelines for establishing numeric values for the criteria.

Furthermore, it would be important to mention the standard methods that meet these criteria. Thereby, member countries would have options for choosing the methods.

- If the Committee does not support the aforementioned suggestion, we would like to present the following comments with respect to the methods of analysis listed in TABLE 1:

Initially, we highlight that methods described as ISO/DIS are methods under revision, thus, it should not be endorsed before the final approval.

TABLE 1- AOAC Official Methods validated in Infant Formula with ISO/IDF References

Commodity	Provision	Method	Principle	Type† Proposed

Infant Formula	Vitamin B12	AOAC 2011.10 ISO/DIS 20634	HPLC	II

It is important to clarify if the method AOAC 2011.10 is equivalent to the method ISO/DIS 20634. If they are equivalent and the performance criteria outlined in the Procedural Manual are met, we are in favour of its endorsement as type II.

Nevertheless, based on the Procedural Manual, 23rd, page 68, we understand that the method AOAC 986.23, currently endorsed as type II in CODEX STAN 234-1999 for this provision with the principle "Turbidimetric", should be endorsed as type III. Thus, countries may use it for control, inspection or regulatory purposes:

"The method selected should be chosen on the basis of practicability and preference should be given to methods which have applicability for routine use" (Procedural Manual, 23rd, page 68).

Commodity	Provision	Method	Principle	Type† Proposed
Infant Formula	Myo- Inositol	AOAC 2011.18 ISO/DIS 20637	LC- pulsed amperometry	II

It is important to clarify if the method AOAC 2011.18 is equivalent to the method ISO/DIS 20637. If they are equivalent and the performance criteria outlined in the Procedural Manual are met, we are in favour of its endorsement as type II.

Commodity	Provision	Method	Principle	Type† Proposed
Infant Formula	Chromium	AOAC 2011.19 ISO/DIS 20649 IDF 235	ICP-MS	II
Infant Formula	Selenium	AOAC 2011.19 ISO/DIS 20649 IDF 235	ICP-MS	II
Infant Formula	Molybdenum	AOAC 2011.19 ISO/DIS 20649 IDF 235	ICP-MS	II

It is important to clarify if the method AOAC 2011.19 is equivalent to the method ISO/DIS 20649|IDF 235. If they are equivalent and the performance criteria outlined in the Procedural Manual are met, we are in favour of its endorsement as type III, given that not all countries are able to use the proposed new methods with the principle ICP-MS in cases of dispute and for calibration purposes.

We are also in favour of keeping the methods of analysis EN 14082 (principle: Graphite furnace atomic absorption after dry ashing) and EN 14627 (principle: HG AAS), listed in Codex Stan 234, for chromium and selenium, as type II.

Commodity	Provision	Method	Principle	Type† Proposed
Infant Formula	Vitamin A Palmitate (Retinyl Palmitate), Vitamin A Acetate (Retinyl Acetate), Total Vitamin E (dl- α - Tocopherol and dl- α - Tocopherol Acetate)	AOAC 2012.10 ISO/DIS 20633	HPLC	II

It is important to clarify if the method AOAC 2012.10 is equivalent to the method ISO/DIS 20633. If they are equivalent and the performance criteria outlined in the Procedural Manual are met, we are in favour of its endorsement as type II.

Nevertheless, based on the Procedural Manual, 23rd, page 68, we suggest that the method AOAC 992.04, currently endorsed as type II in CODEX STAN 234-1999 is endorsed as type III. Thus, countries may use it for control, inspection or regulatory purposes:

“The method selected should be chosen on the basis of practicability and preference should be given to methods which have applicability for routine use” (Procedural Manual, 23rd, page 68).

Commodity	Provision	Method	Principle	Type† Proposed
Infant Formula	Total Fatty Acid Profile	AOAC 2012.13 ISO/DIS 19958 16958 IDF 231	Gas Chromatography	II

We point out that the method ISO/DIS 19958 has not been found. We presume that the correct number is ISO/DIS 16958|IDF231.

Moreover, it is important to clarify if the method AOAC 2012.13 is equivalent to the method ISO/DIS 16958|IDF231. If they are equivalent and the performance criteria outlined in the Procedural Manual are met, we are in favour of its endorsement as type II.

Nevertheless, based on the Procedural Manual, 23rd, page 68, we suggest that the method AOAC 996.06, currently endorsed as type II in CODEX STAN 234-1999 is endorsed as type III. Thus, countries may use it for control, inspection or regulatory purposes:

"The method selected should be chosen on the basis of practicability and preference should be given to methods which have applicability for routine use" (Procedural Manual, 23rd, page 68).

Commodity	Provision	Method	Principle	Type† Proposed
Infant Formula	Iodine	AOAC 2012.15 ISO/DIS 20647 IDF 234	ICP-MS	II

It is important to clarify if the method AOAC 2012.15 is equivalent to the method ISO/DIS 20647|IDF 234. If they are equivalent and the performance criteria outlined in the Procedural Manual are met, we are in favour of its endorsement as type III, given that not all countries are able to use the proposed new methods with the principle ICP-MS in cases of dispute and for calibration purposes.

We are also in favour of keeping the method of analysis AOAC 992.24, listed in Codex Stan 234, for this commodity and provision (Principle: Ion selective electrode), as type II.

Commodity	Provision	Method	Principle	Type† Proposed
Infant Formula	Pantothenic Acid	AOAC 2012.16 ISO/DIS 20639	UHPLC-MS/MS	II

It is important to clarify if the method AOAC 2012.16 is equivalent to the method ISO/DIS 20639. If they are equivalent and the performance criteria outlined in the Procedural Manual are met, we are in favour of its endorsement as type II.

We also suggest that the method of analysis AOAC 992.24, listed in Codex Stan 234, for this commodity and provision (Principle: Microbioassay), currently endorsed as type II in CODEX STAN 234-1999, is endorsed as type III. Thus, countries may use it for control purposes.

Furthermore, the United States of America suggest recommending to CCMAS that the method AOAC 992.17 for pantothenic acid that may be replaced by the methods in Table 1 and are not validated for infant formula be removed or reclassified. However, we point out that this method is not listed in Codex Stan 234 and that it is used for analysis of pesticide residues in vegetables/potatoes. The method currently listed in Codex Stan 234 for pantothenic Acid in infant formula is the method 992.07:

Diquat and Paraquat Residues in Potatoes

Method Type	Quantitative Chemistry
Analyte	Pesticide Residues/Diquat and Paraquat
Analytical Technique	Liquid Chromatographic Method
Equipment	Chromatography/Liquid Chromatography
Matrices	Vegetables/Potatoes
Approved By	AOAC
Method Number	992.17

Pantothenic Acid in Milk-Based Infant Formula

Method Type	Quantitative Microbiology
Analyte	Acids/Pantothenic Acid
Analytical Technique	Microbiological Turbidimetric Method
Equipment	Microbiological, Turbidimeter
Matrices	Infant Formula/Milk-Based Infant Formula
Approved By	AOAC
Method Number	992.07

COLOMBIA

Colombia está de acuerdo con iniciar el trabajo para Métodos de análisis de la Norma para preparados para lactantes y preparados para usos medicinales especiales destinados a los lactantes; y que se solicite remitir al CCMAS ocho métodos de análisis de nutrientes de preparados para lactantes —vitamina B12, mioinositol, cromo, selenio, molibdeno, nucleótidos, vitaminas A y E, perfil de ácidos grasos, yodo y ácido pantoténico— para que éste lleve a cabo una revisión técnica de los mismos, les adjudique un tipo, los ratifique y los incluya en los Métodos de análisis y de muestreo recomendados (CODEX STAN 234-1999).

ECUADOR

English:

General Comments

Ecuador agrees to bring to the attention of the Codex Committee on Methods of Analysis and Sampling the eight methods of nutrient analysis of infant formula. However, Ecuador does not agree to consider the possibility of eliminating the methods that are included in the methods of analysis and sampling recommended (CODEX STAN 234-1999)

Rationale:

Some countries may not be able to adopt new methods of analysis, and, if it is decided to not eliminate methods that are included in the methods of analysis and sampling recommended (CODEX STAN 234-1999), countries would have at least a second option in which to base their methods of analysis, so it is suggested not to remove them, and propose them as a second option.

Español:

Comentarios Generales:

Ecuador está de acuerdo en poner a consideración del Comité de Codex sobre Métodos de Análisis y toma de Muestras los ocho métodos de análisis de nutrientes de preparados para lactantes. Sin embargo, Ecuador no está de acuerdo en considerar la posibilidad de eliminar los métodos que se encuentran incluidos en los Métodos de análisis y de muestreo recomendados (CODEX STAN 234-1999)

Justificación:

Algunos Países podrían no estar en condiciones de adoptar los nuevos métodos de análisis, y, al no eliminar los métodos que se encuentran incluidos en los Métodos de análisis y de muestreo recomendados

(CODEX STAN 234-1999), los países al menos tendrían una base o una opción secundaria en cual sustentar sus métodos de análisis, por lo que se sugiere no eliminarlos, y proponerlos como una opción secundaria.

EUROPEAN UNION

*Mixed competence
Member States vote*

The European Union and its Member States would like to submit the following comments:

The proposed AOAC/ISO/(IDF) methods have been recently validated by an AOAC led consortium of infant formula manufacturers. They represent the current state-of-the-art and as some of the related methods listed in STAN 234 are indeed outdated it is appropriate that CCNFSU requests CCMAS to review them and decide whether they can be endorsed. For some of the provisions contained in STAN 72 methods of analysis are indeed missing in STAN 234. For example, no method has been endorsed and included in STAN 234 for myo-inositol and nucleotides, although the latter are only mentioned under optional ingredients and no minimum/maximum values are given in the standard. For the other provisions mentioned STAN 234 contains endorsed methods and a number of them, in particular the European Norms, are still valid and in use (see overview below).

Provision	Method included in STAN 234	Principle	Method scope
Vitamin B12	AOAC 986.23	Microbiological assay (no validation data available)	Milk/infant formula
Myo-inositol	No method	--	--
Chromium	EN 14082 EN 14083 AOAC 2006.03	AAS dry ashing AAS pressure ashing ICP-OES	Milk Milk Fertilisers
Selenium	AOAC 996.16/17 EN 14627 AOAC984.27	Spectroscopy/Fluorimetry Hydride AAS ICP-OES	Feed/premixes Se not in method scope
Molybdenum	EN 14083	AAS pressure ashing	
5'-Mono-nucleotides	No method	--	--
Vitamin A	EN 12083-1	HPLC-UV	Milk
Vitamin E	AOAC 992.03 EN 12822	HPLC-UV HPLC-UV	Infant formula Milk
Fatty acids	AOAC 996.06 ¹⁾ AOCS Ce 1h-05 ²⁾	GLC-FID GLC-FID	
Iodine	AOAC 992.24	Ion-selective electrode	Infant formula
Pantothenic acid	AOAC 992.07	Microbiological assay	Infant formula

¹⁾ AOAC 996.06 has been designed to determine total fat and has not been validated for the estimation of individual fatty acids, including trans fatty acids.

²⁾ AOCS Ce 1h-05 has been specifically designed and validated for the determination of cis-, trans-, saturated, monounsaturated and polyunsaturated fatty acids in vegetable or non-ruminant oils and fats.

Provision	Proposed amendment	Principle	Remark
Vitamin B12	AOAC 2011.10 ISO/DIS 20634	HPLC-UV	Extensive validation data

Myo-inositol	No method	HPLC-amperometric detection	Extensive validation data
Chromium	AOAC 2011.19 ISO/DIS 20649 IDF 235	ICP-MS	Validation data provided not very informative
Selenium	AOAC 2011.19 ISO/DIS 20649 IDF 235	ICP-MS	Validation data provided not very informative
Molybdenum	AOAC 2011.19 ISO/DIS 20649 IDF 235	ICP-MS	Validation data provided not very informative
5'-Mono-nucleotides	AOAC 2011.20 ISO/DIS 20638	HPLC-UV	AOAC 2011.20 does not contain validation data; however, they are available (J. AOAC International 98, 2015, 971-979); method not suitable for non-fortified infant-formula
Vitamin A	AOAC 2012.10 ISO/DIS 20633	HPLC-UV	AOAC 2012.10 does not contain validation data, while ISO/DIS 20633 does. Furthermore, the standard does not allow to determine all potential forms of vitamin A and E.
Vitamin E	AOAC 2012.10 ISO/DIS 20633	HPLC-UV	AOAC 2012.10 does not contain validation data, while ISO/DIS 20633 does. Furthermore, the standard does not allow to determine all potential forms of vitamin A and E.
Fatty acids	AOAC 2012.13 ISO/DIS 16958 IDF 231	GLC-FID	AOAC 2012.13 does not contain validation data.
Iodine	AOAC 2012.15 ISO/DIS 20647 IDF 234	ICP-MS	Extensive validation data
Pantothenic acid	AOAC 2012.16 ISO/DIS 20639	HPLC-MS	AOAC 2012.16 does not contain validation data, while ISO/DIS 20639 does.

Conclusions and recommendations

As all concerned provisions relate to rationale analytes where the stoichiometry of the compounds concerned is known, the criteria approach is applicable. This would allow keeping the currently used methods in the system, provided they fulfil the required criteria, and let analysts choose among those methods that best meet their needs.

No validation data are available for the determination of vitamin B12 by AOAC 986.23 and it could be replaced by the newly developed AOAC 2011.10 as the Type II method if CCNFSDU does not opt for the criteria approach.

For the determination of chromium, selenium and molybdenum appropriate European Standards exist (EN 14082, EN 14083, EN 14627) which should be kept in the Codex system, preferentially by using the criteria approach.

The proposed AOAC/ISO method for vitamin A does not quantify all forms of the vitamin, only retinyl palmitate and retinyl acetate, while the provisions of STAN 72 relate to all-trans-retinol. Since no saponification is foreseen in the AOAC/ISO method, naturally present retinyl esters of milk fat escape determination. Regarding vitamin E STAN 72 relates to d- α -tocopherol, while the measurands in the

AOAC/ISO standard is dl- α-tocopherol and dl- α-tocopheryl acetate, which have a different biological activity compared to d-α-tocopherol. Moreover, other forms of vitamin E such as β-, γ-, δ-tocopherol are not covered by the proposed AOAC/ISO standard. Therefore, CCNFSDU may be invited to specify to greater detail the provision for vitamin E, in particular which vitamers are considered to represent vitamin E. For this reason it is not recommended to request submission of AOAC 2012.10/ISO/DIS 20633 for review to CCMAS. In case, the committee decides otherwise, the criteria approach is recommended since appropriate European Standards (EN 12083-1, EN 12822) exist and are in use.

For the determination of fatty acids by AOAC 2012.13/ISO/DIS 16958/IDF 231 no validation data were found in AOAC 2012.13; however, they may be included in the equivalent ISO and IDF standards.

INDONESIA

In principle Indonesia agrees with the proposal of Methods of analysis in the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CODEX STAN 72-1981)

MALI

Problème: Méthodes officielles de l'AOAC validées dans les préparations destinées aux nourrissons avec des références ISO/DIS

Position: Le Mali soutient la mise à jour des méthodes de tests tels que proposés. Nous recommandons qu'au lieu du Projet de norme international (DIS), le comité entre en liaison avec le Secrétariat de l'Organisation internationale de Normalisation (ISO) pour confirmer le statut de DIS. S'ils sont encore sous forme de projet, le Mali soutient seulement le texte publié de l'AOAC et le maintien d'ISO/DIS.

Justification: La mise à jour de la méthode d'essai facilitera l'analyse des produits destinés aux nourrissons sur base d'informations scientifiques actualisées et d'équipements modernes. Cependant, l'adoption d'un projet de norme n'est pas acceptable parce que le texte final peut changer en fonction de la discussion au sein du processus de l'ISO comme cela figure généralement dans leurs avertissements sur les projets de normes, d'où l'importance d'adopter des textes définitifs.

MEXICO

México agradece la oportunidad de realizar comentarios al documento **CX/NFSDU 15/37/10**, respecto a los Métodos de análisis de la *Norma para preparados para lactantes y preparados para usos medicinales especiales destinados a los lactantes* (CODEX STAN 72-1981), correspondiente al Tema 11 de la Agenda de la próxima reunión del CCNFSDU.

Determinación	Método actual CODEX STAN 234-1999	Método propuesto por USA	Comentarios
Vitamina B12	AOAC 952.20 Microbioensayo	AOAC 2011.10 HPLC-UV Propuesta: Tipo II	De acuerdo con establecer el método AOAC 2011.10 y con su clasificación como <u>Tipo II</u> , en función de que el método microbiológico para esta determinación es muy laborioso como método de rutina. Proponemos que el AOAC 952.20 se mantenga clasificado como <u>Tipo III</u> ,
Mioinositol	No existe	AOAC 2011.18 HPLC-PAD Propuesta: Tipo II	De acuerdo con el método propuesto AOAC 2011.18 . Sin embargo se propone que se clasifique como <u>Tipo III</u> . Lo anterior dado que uno de los Criterios para la selección de Métodos de Análisis menciona que <i>se preferirán los métodos que puedan aplicarse para uso habitual</i> y en México no se tiene implementado por el momento.
Cromo	AOAC 2006.03 Absorción Atómica-	AOAC 2011.19 ICP-MS	Se sugiere mantener los métodos actuales y su clasificación como <u>Tipo II</u> .

	Horno de Grafito	Propuesta: Tipo II	
Selenio	AOAC 2006.03 Absorción Atómica-Generador de Hidruros	AOAC 2011.19 ICP-MS Propuesta: Tipo II	El método AOAC 2011.19 debería ser clasificado como <u>Tipo III</u> , con base en los Criterios para la selección de Métodos de Análisis sobre la <i>practicabilidad</i> , por el alto costo de los equipos. Aunque el método propuesto (ICP-MS) permite efectuar el análisis de los tres minerales en la misma corrida, la inversión para su adquisición es alta y son pocos los laboratorios que cuentan con él.
Molibdeno	AOAC 2006.03 Absorción Atómica-Horno de Grafito	AOAC 2011.19 ICP-MS Propuesta: Tipo II	
5'-Mononucleotidos	No existe	AOAC 2011.20 LC-UV Propuesta: Tipo II	Estamos de acuerdo con su adopción así como su clasificación como <u>Tipo II</u> , ya que se requiere de un equipo de cromatografía de líquidos básico.
Vitaminas A y E	EN 12823-1 EN 12821 HPLC-UV	AOAC 2012.10 HPLC-UV HPLC-FL Propuesta: Tipo II	Estamos de acuerdo con su adopción, así como su clasificación como <u>Tipo II</u> . Para el método actual se requiere de dos metodologías diferentes. Con el AOAC 2012.10 es un solo método y se hace una sola preparación y un solo tratamiento de la muestra, solo que se requieren de dos detectores, uno de ultravioleta y otro de fluorescencia.
Perfil de ácidos grasos	AOAC 996.06 GC-FID	AOAC 2012.13 GC-FID Propuesta: Tipo II	Estamos de acuerdo con su adopción, así como su clasificación como <u>Tipo II</u> , ya que con este método, no se requiere la extracción de la grasa de la muestra, lo cual disminuye los tiempos de análisis. El equipo requerido de Cromatografía de Gases es el mismo con detector de Ionización de Flama.
Yodo	AOAC 992.24 Ion selectivo	AOAC 2012.15 ICP-MS Propuesta: Tipo II	Sugerimos mantener el método AOAC 992.24 de ion selectivo como <u>Tipo II</u> , ya que es un método más práctico y económico. El método AOAC 2012.15 debería ser clasificado como <u>Tipo III</u> , con base en los Criterios para la selección de Métodos de Análisis sobre la <i>practicabilidad</i> , por el alto costo de los equipos.
Ácido pantoténico	No existe	AOAC 2012.16 Ultra HPLC-MS/MS Propuesta: Tipo II	La inversión para la adquisición del equipo de Ultra HPLC-MS/MS es muy alta. Por lo que sugerimos que el método AOAC 2012.16 se incluya clasificado como <u>Tipo III</u> , con base en los Criterios para la selección de Métodos de Análisis sobre la <i>practicabilidad</i> , por el alto costo de los equipos. Por otra parte, sugerimos solicitar al CCMAS la evaluación de los métodos

			utilizados actualmente para la determinación del Ácido pantoténico: AOAC 992.07 para Preparados complementarios y el AOAC 945.74 para alimentos especiales
--	--	--	--

MOROCCO

English:

Morocco believes that the new methods described in Table 1 and especially those concerning mineral elements, ie, chromium, selenium, molybdenum and iodine, are methods that are based on the technique of emission Atomic ICP-MS. Given the fact that this material is extremely expensive for some countries, and the determination of these elements particularly chromium, selenium and molybdenum can be performed with high sensitivity by the technique of atomic absorption spectrometry (Graphite furnace for the determination of Cr and Mo, or hydride generation for the determination of Se) which is less expensive than the ICP-MS, we propose to the committee, to consider in addition to the proposed methods, other methods based on the technique of atomic absorption spectrometry ; This can be used by the countries that do not have the ICP-MS.

Justification:

The high cost of ICP-MS equipment is main barrier to the use of this method by developing countries. For this, we should think of other methods that can be used and reliable and it is the case of the atomic absorption spectrophotometer.

Français:

Le Maroc estime que les nouvelles méthodes décrites dans le tableau 1 et surtout celles qui concernent les éléments minéraux, à savoir, le chrome, le sélénium, le molybdène et l'iode , sont des méthodes qui se basent sur la technique de l'émission atomique ICP-MS. Sachant que cet instrument est extrêmement cher pour certains pays , et que la détermination de ces éléments surtout le chrome , sélénium et molybdène peut être effectuée avec une grande sensibilité par la technique de la spectrométrie d'absorption atomique (technique du four à graphite pour le chrome et molybdène et technique du générateur d'hydrures pour le sélénium) et qui ne coutent pas aussi cher que l'ICP-MS, pour cette raison, nous proposons au comité d'envisager , en plus des méthodes proposées , des méthodes qui se basent sur la technique de la spectrométrie d'absorption atomique qui seront utilisées par les laboratoires qui ne disposent pas de L'ICP-MS .

Justification :

La cherté du matériel ICP-MS constitue une entrave à l'utilisation de cette méthode par les pays en voie de développement. Pour cela, il faudrait penser à d'autres méthodes que l'on peut utiliser qui soient aussi fiables et c'est le cas de la spectrophotométrie d'absorption atomique.

AFRICAN UNION

Issue: AOAC Official Methods validated in Infant Formula with ISO/IDF References

Position: AU supports the updating of the methods of tests as proposed. AU recommends that rather than Draft International Standards (DIS), the committee liaise with ISO secretariat to confirm the status of DIS. If they are still in draft form, AU supports only the published text of AOAC and IDF and hold the ISO/DIS

Rationale: Updated method of test will facilitate the analysis of infants products based on updated science and modern equipments. However, adoption of a draft standard is not acceptable because the final text may change depending on the discussion within the ISO process as usually indicated in their disclaimers to the draft standards, and hence the importance of adopting the final texts.